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VIA ECF AND FEDERAL EXPRESS
Honorable Dennis M. Cavanaugh, U.S.D.J.
United States District Court for the District of New Jersey
U.S. Post Office & Courthouse, Room 451
1 Federal Squire
Newark, NJ 07102

Re: Eli Lilly and Company v. Actavis Elizabeth LLC et al.
Civil Action No. 07-3770 (DMC)(MF)

Dear Judge Cavanaugh,

Plaintiff Eli Lilly and Company ("Lilly") respectfully brings to the Court's attention an opinion that was issued on January 26, 2010, after Lilly filed its Motion for Reconsideration, or in the Alternative, Motion for Certification Pursuant to 28 U.S.C. § 1292(b) (D.E. 500 (hereinafter, the "Motion for Reconsideration")). The opinion, attached hereto as Exhibit 1, was issued by Judge Robinson of the United States District Court for the District of Delaware in *Cancer Research Technology v. Barr Labs., Inc.*, Civ. No. 07-457-SLR, and provides further support for Lilly's assertions in its Motion for Reconsideration that an applicant may rely on data generated subsequent to the filing date of a patent application to substantiate an assertion of utility in the specification.

In *Cancer Research*, defendant Barr Laboratories, Inc. (which is a wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc., a defendant in the instant case), had argued that the patent-in-suit was unenforceable because the applicant had unreasonably delayed the prosecution of its patent application. (Slip Op. at 17.) Plaintiff Cancer Research Technology argued that the delay was attributable to the PTO because the patent examiners required human clinical data and, absent such data, would not issue a patent. (*Id.*) In her opinion, Judge Robinson stated that "If [the applicant] believed that the utility rejection was valid, it could have pursued a partner to run human trials and obtain the data that the PTO required." (*Id.* at 24 n.26.) Thus, Judge Robinson acknowledged the propriety of submitting data generated after the application's filing date to substantiate an assertion of utility.[1]

[1] Indeed, in ultimately allowing the patent-in-suit in *Cancer Research*, the examiner had relied on an article published five years after the filing of the application as evidence of the utility of the claimed invention. (*Id.* at 15.)

Judge Robinson was also the author of the opinion in *In re '318 Patent Infring. Litig.*, 578 F. Supp. 2d. 711 (D. Del. 2008), which was affirmed by the Court of Appeals for the Federal Circuit in *In re '318 Patent Infring. Litig.*, 583 F.3d 1317 (Fed. Cir. 2009). Judge Robinson's opinion in *Cancer Research* makes clear that her opinion in *In re '318* could not have held that post-filing test results cannot be used to substantiate an assertion of utility in the specification.

Finally, Lilly notes that in its post-trial briefing in *Cancer Research*, Barr (which by then had been acquired by Teva) advocated the position espoused by Lilly in its pending Motion for Reconsideration:

> In any event, the cases relied on by Plaintiff do not support the incredibly sweeping proposition that post-filing information is irrelevant to enablement. Quite the contrary. *In re Brana* held that *in vivo* test results "against L1210 tumor cells" were relevant to the enablement analysis *despite* the test results being reported *after* the patent filing date. 51 F.3d 1560, 1567 n.19 (Fed. Cir. 1995). And *Hogan,* on which Plaintiffs so heavily rely, explained that while enablement is judged as of the date of filing, the use of "*later knowledge* about art-related facts existing on the filing date" is permissible. *In re Hogan,* 559 F.2d 595, 605 (C.C.P.A. 1977); *see also Plant Genetic Systems, N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1344 (Fed. Cir. 2003) (using post-filing information in enablement analysis); *Monsanto Co. v. Bayer Bioscience N.V.*, 2005 WL 5989796, at *16 (E.D. Mo. Oct. 28, 2005) (same).

Barr's Reply Post-Trial Brief at 23 n.14 (attached hereto as Exhibit 2) (emphasis in original); *see also id.* at 10 ("during the prosecution, Applicants could have . . . provided the [post-filing] animal testing data that ultimately persuaded Examiner Dentz to allow the patent, but did not do so."); Barr's Opening Post-Trial Brief at 29 (attached hereto as Exhibit 3) ("even if there had been a requirement for Phase II clinical data [to overcome the utility rejection], Applicants also had [post-filing] Phase II testing data for mitozolomide that they could have submitted.").

Respectfully submitted,

/s/ John F. Brenner

John F. Brenner

Enclosures
cc: Counsel of Record